of maturation comparable to that achieved at an age of 42 days after birth in a mouse or rat.

103. A method of reducing the incidence or severity of a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at specific times after birth, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where said mammal is human, and at least one immunogen other than BCG or pertussis is administered before 42 days after birth.

104. The kit of claim 27 where the mammal is human and the disorder is an autoimmune disease.

105. The kit of claim 59 where the mammal is human and the disorder is an autoimmune disease.

106. The method of claim 103 in which at least one immunogen other than smallpox is administered before 42 days after birth.

107. The kit of claim 27, said kit further comprising a label for each container indicating the identity and amount of each immunogen in such container.

108. The kit of claim 59, said kit further comprising a label for each container indicating the identity and amount of each immunogen in such container.--

REMARKS

1. New claims 107 and 108 further limit 27 and 59 by providing that the label of the containers of the kits indicates the identity and amount of each immunogen. Under U.S. law, the "label" of a drug must bear the established name, and, if the drug is a prescription drug, the quantity, of each active

ingredient. See Food, Drug and Cosmetic Act sec. 502(e)(1) [21 U.S.C. §352(e)(1)].

This label information is akin to the volumetric indicia in Miller.

2. New kit claim 102 is motivated by §4(i) of the office action, and is based on page 29, lines 13-19.

3. New method claim 103 is based on original claim 32, but requires that the subject be human (cp. original claim 16) and that at least one immunogen be one other than BCG (cp. original PCT claim 1, final limitation) or pertussis (cp. original claim 5, as well as claim 29).

The purpose of this claim is similar to that of the March 25 amendment to claim 32, i.e., to further distinguish Adams (1947) and Provenzano (1965), but we hope that it may be more palatable to the Examiner.

4. New claims 104 and 105 combine the previously presented "human" and "autoimmune disease" limitations.

5. New claim 106, by excluding smallpox as sole immunogen, follows the lead of original PCT claim 7.

6. The Examiner is respectfully reminded that Applicant is still awaiting a supervisory decision on the REQUEST FOR WITHDRAWAL OF FINALITY AND/OR VACATING OF LAST ACTION filed May 4, 1999. If that request is granted, then this amendment should be entered as a matter of right.

Respectfully submitted,

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